

Melengestrol acetate in mg/head/day	Combination in mg/head/day	Indications for use	Limitations	Sponsor
(ix) 0.25 to 0.5	Tylosin 60 to 90	Heifers fed in confinement for slaughter: As in paragraph (e)(1)(i) of this section; and for reduced incidence of liver abscesses caused by <i>F. necrophorum</i> and <i>Actinomyces (Corynebacterium) pyogenes</i> ..	To administer 0.25 to 0.5 mg melengestrol acetate with 60 to 90 mg tylosin/head/day:.. 1. Add 0.5 to 2.0 lb/head/day of a liquid or dry medicated feed containing 0.125 to 1.0 mg melengestrol acetate/lb to a medicated feed containing 8 to 10 g tylosin per ton; or. 2. Add 0.5 to 2.0 lb/head/day of a liquid or dry medicated feed containing 0.125 to 1.0 mg melengestrol acetate/lb to 4.5 to 18 pounds of a dry medicated feed containing 10 to 40 g tylosin per ton; or. 3. Add 0.5 to 2.0 lb/head/day of a liquid or dry medicated feed containing 0.125 to 1.0 mg melengestrol acetate (from a dry Type A article) plus 45 to 180 mg tylosin/lb to a ration of nonmedicated feed.. Tylosin as tylosin phosphate provided by No. 000986 in § 510.600(c) of this chapter..	000009

(2) Melengestrol may also be used with ractopamine alone or in combination as in § 558.500 of this chapter.

[42 FR 28535, June 3, 1977, as amended at 46 FR 18967, Mar. 27, 1981; 49 FR 39842, Oct. 11, 1984; 50 FR 1843, Jan. 14, 1985; 50 FR 16228, Apr. 25, 1985; 51 FR 7398, Mar. 3, 1986; 51 FR 36222, Oct. 9, 1986; 52 FR 2685, Jan. 26, 1987; 52 FR 33804, Sept. 8, 1987; 53 FR 27959, July 26, 1988; 55 FR 31828, Aug. 6, 1990; 57 FR 5053, Feb. 12, 1992; 59 FR 41241, Aug. 11, 1994; 60 FR 11028, Mar. 1, 1995; 62 FR 8373, Feb. 25, 1997; 62 FR 14304, Mar. 26, 1997; 63 FR 27845, May 21, 1998; 63 FR 41191, Aug. 3, 1998; 63 FR 66018, Dec. 1, 1998; 67 FR 47688, July 22, 2002; 69 FR 30198, May 27, 2004; 69 FR 51174, Aug. 18, 2004; 70 FR 2566, Jan. 14, 2005]

§ 558.348 Mibolerone.

(a) *Approvals.* To No. 000009 in § 510.600(c) of this chapter for a canned dog food, each 6½ ounce can containing 30 or 60 micrograms of mibolerone.

(b) *Conditions of use*—(1) *Amount.* 30 micrograms for animals weighing up to 25 pounds; 60 micrograms for animals weighing 26 to 50 pounds; 120 micrograms for animals weighing 51 to 100 pounds; 180 micrograms for animals weighing over 100 pounds, or German Shepherds or German Shepherd mix weighing 30 to 80 pounds.

(2) *Indications for use.* For the prevention of estrus (heat) in adult female dogs not intended primarily for breeding purposes.

(3) *Limitations.* Administer daily at least 30 days before expected initiation of heat and continue as long as desired, but for not more than 12 months. Mibolerone should not be used in bitches before first estrous period or in purebred Bedlington terriers. It is not intended for animals being used primarily for breeding purposes. Use orally in adult female dogs only. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[47 FR 6617, Feb. 16, 1982]

§ 558.355 Monensin.

(a) *Specifications.* Monensin, as the base or the sodium salt, contains a minimum of 90 percent monensin activity derived from monensin A and a minimum of 95 percent derived from monensin A plus B. Using thin layer chromatography, the R_f value must be comparable to a reference standard (the R_f value is the distance the spots travel from the starting line divided by the distance the solvent front travels from the starting line), or, using High Performance Liquid Chromatography,

the factor distribution of monensin Factor A or B is calculated as the percentage of total biopotency of all peaks. The loss on drying is not more than 10 percent when dried in vacuum at 60 °C for 2 hours.

(b) *Approvals.* Approvals for Type A medicated articles containing the specified levels of monensin activity granted to firms identified by sponsor numbers in § 510.600(c) of this chapter for the conditions of use indicated in paragraph (f) of this section are as follows:

(1) To 000986: 36.3 (for export only), 44, 45, or 60 grams per pound, paragraphs (f) (1)(i) and (4) of this section.

(2) To 000986: 110 grams per lb., paragraphs (f)(1) (i), (iii), (iv), (v), (ix), and (x).

(3) To 000986: 44 grams per lb. with 18 grams per lb. of roxarsone, 110 grams per lb. with 45 grams per lb. of roxarsone, paragraph (f)(1)(ii).

(4) To 000986: 45 and 60 grams per pound, as monensin sodium, paragraph (f)(2) of this section.

(5) To 066104: 45 and 60 grams per pound, as monensin sodium provided by No. 000986, paragraphs (f)(1)(xiii), (xx), and (xxi) of this section.

(6) To 000986: 45 and 60 grams per pound, as monensin sodium, paragraph (f)(5) of this section.

(7) To 000986: 20, 30, 45, 60, 80, and 90.7 grams per pound, as monensin sodium, paragraph (f)(3) of this section.

(8) To 046573: 45 and 60 grams per pound, as monensin sodium provided by No. 000986, paragraph (f)(1)(xiv) of this section.

(9) To 046573: 45 and 60 grams per pound, as monensin sodium provided by No. 000986, paragraphs (f)(1)(xv) and (xvi) of this section.

(10) To 057926: 45 and 60 grams per pound, as monensin sodium, paragraph (f)(1)(xvii) of this section.

(11) To 046573: 45 and 60 grams per pound, as monensin sodium provided by No. 000986, paragraphs (f)(1)(xiv), (xviii), (xix), (xxiii), (xxiv), (xxv), (xxvi), and (xxvii) of this section.

(12) To 066104: 45 and 60 grams per pound, as monensin sodium provided by No. 000986, paragraph (f)(1)(xxii) of this section.

(13) To 021930: 60 and 80 grams per pound, paragraph (f)(3)(v) of this section.

(14) To 000986: 60, 80, and 90.7 grams per pound, as monensin sodium, paragraph (f)(6) of this section.

(c) [Reserved]

(d) *Special considerations.* (1) Type C chicken feed containing monensin as the mycelial cake shall bear an expiration date of 90 days after its date of manufacture.

(2) Type C cattle feeds containing 30 grams or less monensin sodium per ton shall bear an expiration date of 30 days after its date of manufacture.

(3) Type C goat feeds shall bear an expiration date of 30 days after date of manufacture.

(4) [Reserved]

(5) Liquid Type B feeds shall bear an expiration date of 8 weeks after its date of manufacture.

(6) The labeling of all formulations containing monensin shall bear the following caution statement: Do not allow horses or other equines access to feed containing monensin. Ingestion of monensin by horses has been fatal.

(7) The labeling of all Type A articles and Type B feeds (liquid and dry) containing monensin intended for use in cattle shall bear, in addition to the caution statement in paragraph (d)(6) of this section, the following caution statements:

(i) Monensin medicated cattle feed is safe for use in cattle only. Consumption by unapproved species may result in toxic reactions;

(ii) Feeding undiluted or mixing errors resulting in high concentrations of monensin has been fatal to cattle.

(iii) Must be thoroughly mixed in feeds before use;

(iv) Do not feed undiluted;

(v) Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result.

(vi) A withdrawal time has not been established for preruminating calves. Do not use in calves to be processed for veal.

(8) The labeling of complete feeds containing monensin intended for use in cattle shall bear the caution statements specified in paragraphs (d) (6) and (7) (i) and (v) of this section.

(9) The labeling of Type A articles containing monensin intended for use in chickens shall bear the caution

statements specified in paragraphs (d) (6) and (7) (iii) and (iv) of this section.

(10) The labeling of all Type A articles and Type B feeds (liquid and dry) containing monensin intended for use in goats shall bear, in addition to the caution statement in paragraph (d)(6) of this section, the following caution statements:

(i) Monensin medicated goat feed is safe for use in goats only. Consumption by unapproved species may result in toxic reactions.

(ii) Feeding undiluted or mixing errors resulting in high concentrations of monensin could be fatal to goats.

(iii) Must be thoroughly mixed in feeds before use.

(iv) Do not feed undiluted.

(v) Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result.

(11) The labeling of complete feeds containing monensin intended for use in goats shall bear the caution statements specified in paragraphs (d)(6) and (d)(10) (i) and (v) of this section.

(12) Mixing directions for liquid feeds requiring recirculation or agitation:

(i) For liquid feeds stored in recirculating tank systems: Recirculate immediately prior to use for not less than 10 minutes, moving not less than 1 percent of the tank contents per minute from the bottom of the tank to the top. Recirculate daily as described even when not used.

(ii) For liquid feeds stored in mechanical, air, or other agitation-type tank systems: Agitate immediately prior to use for not less than 10 minutes, creating a turbulence at the bottom of the tank that is visible at the top. Agitate daily as described even when not used.

(13) The labeling of Type B and Type C (liquid and dry) medicated feeds intended for use in dairy cows shall bear the following caution statements: You may notice: Reduced voluntary feed intake in dairy cows fed monensin. This reduction increases with higher doses of monensin fed. Rule out monensin as the cause of reduced feed intake before attributing to other causes such as illness, feed management, or the environment. Reduced milk fat percentage in dairy cows fed monensin. This reduc-

tion increases with higher doses of monensin fed. Increased incidence of cystic ovaries and metritis in dairy cows fed monensin. Reduced conception rates, increased services per animal, and extended days open and corresponding calving intervals in dairy cows fed monensin.

(e) *Related tolerances.* See § 556.420 of this chapter.

(f) *Conditions of use.* It is used as follows:

(1) *Broiler chickens*—(i) *Amount per ton.* Monensin, 90–110 grams.

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(b) *Limitations.* Do not feed to laying chickens; feed continuously as the sole ration; in the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain; as monensin or monensin sodium.

(ii) *Amount per ton.* Monensin, 90–110 grams, plus roxarsone 45.4 grams (0.005 percent).

(a) *Indications for use.* Growth promotion and feed efficiency, improving pigmentation; as an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati* and *E. maxima*.

(b) *Limitations.* Do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as monensin or monensin sodium.

(iii) *Amount per ton.* Monensin, 90–110 grams plus bacitracin, 5–25 grams.

(a) *Indications for use.* For increased rate of weight gain and improved feed efficiency; as an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(b) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; in the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain; as bacitracin methylene disalicylate provided by No. 046573 in § 510.600(c) of this chapter; as monensin sodium.

(iv) *Amount per ton.* Monensin, 90–110 grams plus bacitracin, 10 grams.

(a) *Indications for use.* For increased rate of weight gain and improved feed efficiency; as an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(b) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; in the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain; as zinc bacitracin provided by No. 046573 in § 510.600(c) of this chapter; as monensin sodium.

(v) *Amount per ton.* Monensin, 90–110 grams plus bacitracin, 10–30 grams.

(a) *Indications for use.* For improved feed efficiency; as an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(b) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; in the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain; as zinc bacitracin provided by No. 046573 in § 510.600(c) of this chapter; as monensin sodium.

(vi) *Amount per ton.* Monensin, 90 to 110 grams plus bambermycins, 1 to 2 grams. See § 558.95(b)(1)(vi).

(vii) *Amount per ton.* Monensin, 90 to 110 grams plus bambermycins, 1 gram plus roxarsone, 22.7 to 45.4 grams (.0025 to .005 percent). See § 558.95(b)(1)(vii).

(viii) *Amount per ton.* Monensin, 90 to 110 grams plus oxytetracycline, 200 grams.

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; and for the control of complicated chronic respiratory disease (CRD or air-sac infection) caused by *Mycoplasma gallisepticum* and *Escherichia coli*.

(b) *Limitations.* In the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain; do not feed to laying chickens; feed continuously as sole ration; as monensin sodium.

(ix) *Amount per ton.* Monensin, 90–110 grams plus lincomycin, 2 grams.

(a) *Indications for use.* For increase in rate of weight gain and improved feed efficiency; as an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(b) *Limitations.* Do not feed to laying chickens; to be fed as a sole ration; in the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain; as monensin sodium.

(x) *Amount per ton.* Monensin, 90–110 grams plus lincomycin, 2 grams and roxarsone, 15–45 grams.

(a) *Indications for use.* For increase in rate of weight gain; as an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(b) *Limitations.* Do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as roxarsone provided by No. 046573, § 510.600(c) of this chapter; as monensin sodium provided by No. 000986, § 510.600(c) of this chapter; as lincomycin provided by No. 000009, § 510.600(c) of this chapter; as a combination provided by No. 000009, § 510.600(c) of this chapter.

(xi) *Amount per ton.* Monensin, 90 to 110 grams, plus lincomycin, 2 grams and roxarsone, 15 to 30 grams.

(a) *Indications for use.* For increase in rate of weight gain, improved feed efficiency, improved pigmentation, and as an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati* and *E. maxima*.

(b) *Limitations.* Do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as roxarsone provided by No. 046573 in § 510.600(c) of this chapter; as monensin sodium provided by No. 000986 in § 510.600(c) of this chapter; as lincomycin provided by No. 000009 in § 510.600(c) of this chapter; as a combination provided by No. 000009 in § 510.600(c) of this chapter.

(xii) *Amount per ton.* Monensin, 90 to 110 grams, plus bacitracin methylene disalicylate, 10 to 25 grams, and roxarsone, 11.3 to 45.4 grams.

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. maxima*, and *E. mivati*; for increased rate of weight gain and for improved feed efficiency.

(b) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as monensin sodium provided by No. 000986 in §510.600 of this chapter; as bacitracin methylene disalicylate provided by No. 046573 in §510.600 of this chapter; as roxarsone provided by No. 011526 or 046573 in §510.600 of this chapter.

(xiii) *Amount per ton.* Monensin, 90 to 110 grams, plus 5 grams virginiamycin.

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. maxima*, and *E. mivati*; for increased rate of weight gain and improved feed efficiency.

(b) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; as monensin sodium provided by No. 000986 in §510.600 of this chapter; virginiamycin provided by No. 066104 in §510.600 of this chapter.

(xiv) *Amount per ton.* Monensin, 90 to 110 grams, plus 500 grams chlortetracycline.

(a) *Indications for use.* As an aid in the reduction of mortality due to *Escherichia coli* infections susceptible to such treatment. As an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(b) *Limitations.* Do not feed to laying chickens; feed for 5 days as the sole ration; withdraw 24 hours before slaughter; in the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain; not to be fed continuously for more than 5 days; as monensin sodium; as chlortetracycline hydrochloride provided by Nos. 046573 and 048164 in §510.600(c) of this chapter.

(xv) *Amount per ton.* Monensin, 90 to 110 grams, plus bacitracin zinc, 10 grams, and roxarsone, 15 grams (0.0017 percent).

(a) *Indications for use.* For increase in rate of weight gain; for the prevention of coccidiosis caused by *Eimeria*

necatrix, *E. tenella*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*.

(b) *Limitations.* Do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; feed must be used within 4 weeks of manufacture; as monensin sodium; as bacitracin zinc provided by No. 046573 in §510.600(c) of this chapter; as roxarsone provided by No. 046573 in §510.600(c) of this chapter.

(xvi) *Amount per ton.* Monensin, 90 to 110 grams, plus bacitracin zinc, 4 to 50 grams, and roxarsone, 15 to 45.4 grams (0.0017 percent to 0.005 percent).

(a) *Indications for use.* For improved feed efficiency; for improved pigmentation by enhancing carotenoid and xanthophyll utilization; for the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*.

(b) *Limitations.* Do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; feed must be used within 4 weeks of manufacture; as monensin sodium; as bacitracin zinc provided by No. 046573 in §510.600(c) of this chapter; as roxarsone provided by No. 046573 in §510.600(c) of this chapter.

(xvii) *Amount per ton.* Monensin, 90 to 110 grams plus bambermycins, 1 to 2 grams plus roxarsone, 22.7 to 45.4 grams (0.0025 to 0.005 percent). See §558.95(b)(1)(xiii) of this chapter.

(xviii) *Amount per ton.* Monensin, 90 to 110 grams, plus bacitracin methylene disalicylate, 50 grams, and roxarsone, 22.7 to 34.0 grams (0.0025 percent to .00375 percent).

(a) *Indications for use.* For increase in rate of weight gain and improved feed efficiency; as an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*; as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium spp* or other organisms susceptible to bacitracin methylene disalicylate.

(b) *Limitations.* Do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as monensin sodium provided by No.

000986 in § 510.600(c) of this chapter; as bacitracin methylene disalicylate provided by No. 046573 in § 510.600(c) of this chapter; as roxarsone provided by No. 046573 in § 510.600(c) of this chapter.

(xix) *Amount per ton.* Monensin, 90 to 110 grams, plus bacitracin methylene disalicylate, 50 grams, and roxarsone, 22.7 to 45.4 grams (0.0025 percent to .005 percent).

(a) *Indications for use.* For increased rate of weight gain; as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp or other organisms susceptible to bacitracin methylene disalicylate; as an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*.

(b) *Limitations.* Do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as monensin sodium provided by No. 000986 in § 510.600(c) of this chapter; as bacitracin methylene disalicylate provided by No. 046573 in § 510.600(c) of this chapter; as roxarsone provided by No. 046573 in § 510.600(c) of this chapter.

(xx) *Amount per ton.* Monensin, 90 to 110 grams, plus virginiamycin, 5 to 15 grams, and roxarsone, 22.7 grams (0.0025 percent).

(a) *Indications for use.* For increase in rate of weight gain; as an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*.

(b) *Limitations.* Do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as monensin sodium provided by No. 000986 in § 510.600(c) of this chapter; as virginiamycin provided by No. 066104 in § 510.600(c) of this chapter; roxarsone provided by Nos. 046753 and 011526 in § 510.600(c) of this chapter.

(xxi) *Amount per ton.* Monensin, 90 to 110 grams, plus virginiamycin, 5 to 15 grams.

(a) *Indications for use.* For increase in rate of weight gain; as an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*.

(b) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; as monensin sodium provided by No. 000986 in § 510.600 of this chapter; virginiamycin provided by No. 066104 in § 510.600 of this chapter.

(xxii) *Amount per ton.* Monensin, 90 to 110 grams plus oxytetracycline, 500 grams.

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. Mivati*, and *E. maxima*; as an aid in the reduction of mortality due to air-sacculitides (air-sac infection) caused by *Escherichia coli* sensitive to oxytetracycline.

(b) *Limitations.* Feed for 5 days as sole ration. Do not feed to laying chickens. Withdraw 24 hours before slaughter. As monensin sodium provided by No. 000986 in § 510.600(c) of this chapter. As mono-alkyl (C₈-C₁₈) trimethylammonium oxytetracycline provided by No. 066104 in § 510.600(c) of this chapter.

(xxiii) *Amount per ton.* Monensin, 90 to 110 grams, plus bacitracin zinc, 4 to 50 grams, and roxarsone, 22.7 to 45.4 grams (0.0025 percent to 0.005 percent).

(a) *Indications for use.* For improved feed efficiency; as an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*.

(b) *Limitations.* Do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as monensin sodium provided by No. 000986 in § 510.600(c) of this chapter; as bacitracin zinc provided by No. 046573 in § 510.600(c) of this chapter; as roxarsone provided by No. 046573 in § 510.600(c) of this chapter.

(xxiv) *Amount per ton.* Monensin, 90 to 110 grams, plus bacitracin methylene disalicylate, 4 to 50 grams.

(xxv) *Amount per ton.* Monensin, 90 to 110 grams plus bacitracin, 4 to 50 grams.

(a) *Indications for use.* For increased rate of weight gain and improved feed efficiency; as an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(b) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; in the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain; as bacitracin zinc provided by No. 046573 in § 510.600(c) of this chapter, as monensin sodium.

(xxvi) *Amount per ton.* Monensin 90 to 110 grams plus bacitracin 100 to 200 grams and roxarsone 22.7 to 34.0 grams.

(a) *Indications for use.* As an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin methylene disalicylate; as an aid in the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*; for increased rate of weight gain and improved feed efficiency.

(b) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Use as sole source of organic arsenic. Withdraw 5 days before slaughter. Do not feed to laying hens. To control necrotic enteritis, start medication at first clinical signs of disease. The dosage range permitted provides for different levels based on the severity of infection. Use continuously for 5 to 7 days or as long as clinical signs persist, then reduce dosage to prevention level. Animals should have access to drinking water at all times. Drug overdosage or lack of water may result in leg weakness. As roxarsone and bacitracin methylene disalicylate provided by No. 046573 in § 510.600(c) of this chapter.

(xxvii) *Amount per ton.* Monensin 90 to 110 grams plus bacitracin 100 to 200 grams and roxarsone 22.7 to 45.4 grams.

(a) *Indications for use.* As an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin methylene disalicylate; as an aid in the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*; for increased rate of weight gain.

(b) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Use as sole source of organic arsenic. Withdraw 5 days before slaughter. Do not feed to laying hens. To control necrotic enteritis, start medication at

first clinical signs of disease. The dosage range permitted provides for different levels based on the severity of infection. Use continuously for 5 to 7 days or as long as clinical signs persist, then reduce dosage to prevention level. Animals should have access to drinking water at all times. Drug overdosage or lack of water may result in leg weakness. As roxarsone and bacitracin methylene disalicylate provided by No. 046573 in § 510.600(c) of this chapter.

(xxviii) *Amount per ton.* Monensin, 90 to 110 grams, plus tylosin phosphate, 4 to 50 grams.

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, for increased rate of weight gain, and improved feed efficiency.

(b) *Limitations.* Feed continuously as sole ration. In the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain. Do not feed to laying chickens. As monensin sodium and tylosin phosphate provided by No. 000986 in § 510.600(c) of this chapter.

(xxix) *Amount per ton.* Monensin, 90 to 110 grams; plus bacitracin methylene disalicylate, 50 grams.

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; and as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

(b) *Limitations.* Feed continuously as sole ration. Do not feed to chickens over 16 weeks of age. Do not feed to laying chickens. As monensin sodium provided by 000986; bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.

(xxx) *Amount per ton.* Monensin, 90 to 110 grams; plus bacitracin methylene disalicylate, 100 to 200 grams.

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; and as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

(b) *Limitations.* Feed continuously as sole ration. Do not feed to chickens over 16 weeks of age. Do not feed to laying chickens. To control necrotic enteritis, start medication at first clinical signs of disease; vary dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 grams per ton). As monensin sodium provided by 000986; bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.

(2) *Turkeys*—(i) *Amount per ton.* Monensin, 54 to 90 grams.

(a) *Indications for use.* For the prevention of coccidiosis in turkeys caused by *E. adenoides*, *E. meleagritidis*, and *E. gallopavonis*.

(b) *Limitations.* For growing turkeys only; as monensin sodium; feed continuously as sole ration. Do not allow horses, other equines, mature turkeys, or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal. Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis.

(ii) *Amount per ton.* Monensin, 54 to 90 grams, and bacitracin methylene disalicylate, 4 to 50 grams.

(a) *Indications for use.* For prevention of coccidiosis caused by *Eimeria adenoides*, *E. meleagritidis*, and *E. gallopavonis*, for increased rate of weight gain, and for improved feed efficiency.

(b) *Limitations.* For growing turkeys only; as monensin sodium; feed continuously as sole ration. Do not allow horses, other equines, mature turkeys or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal. Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis. Bacitracin methylene disalicylate as provided by No. 046573 in § 510.600(c) of this chapter.

(iii) *Amount per ton.* Monensin, 54 to 90 grams, and bacitracin methylene disalicylate, 200 grams.

(a) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria adenoides*, *E. meleagritidis*, and *E. gallopavonis*, and as an aid in the control of transmissible enteritis complicated by organisms susceptible to bacitracin methylene disalicylate.

(b) *Limitations.* For growing turkeys only; as monensin sodium; feed continuously as sole ration. Do not allow horses, other equines, mature turkeys or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal. Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis. Bacitracin methylene disalicylate as provided by No. 046573 in § 510.600(c) of this chapter.

(iv) *Amount per ton.* Monensin, 54 to 90 grams, with virginiamycin, 10 to 20 grams.

(a) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria adenoides*, *E. meleagritidis*, and *E. gallopavonis*, and for increased rate of weight gain and improved feed efficiency in growing turkeys.

(b) *Limitations.* For growing turkeys only. Feed continuously as sole ration. Do not allow horses, other equines, mature turkeys, or guinea fowl access to feed containing monensin. Ingestion of monensin by horses, mature turkeys, and guinea fowl has been fatal. Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis. Virginiamycin as provided by No. 066104 in § 510.600(c) of this chapter.

(v) *Amount per ton.* Monensin, 54 to 90 grams, plus bambermycins, 1 to 2 grams.

(a) *Indications for use.* For the prevention of coccidiosis in turkeys caused by *E. adenoides*, *E. meleagritidis*, and *E. gallopavonis*, and for improved feed efficiency in growing turkeys.

(b) *Limitations.* For growing turkeys only. Feed continuously as sole ration. Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis. Bambermycins as provided by No. 057926 in § 510.600(c) of this chapter.

(vi) *Amount per ton.* Monensin, 54 to 90 grams, plus bambermycins, 2 grams.

(a) *Indications for use.* For the prevention of coccidiosis in turkeys caused by *E. adenoides*, *E. meleagris*, and *E. gallopavonis*, and for increased rate of weight gain and improved feed efficiency in growing turkeys.

(b) *Limitations.* For growing turkeys only. Feed continuously as sole ration. Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis. Bambermycins as provided by No. 057926 in § 510.600(c) of this chapter.

(3) *Cattle*—(i) *Amount per ton.* Monensin, 5–30 grams.

(a) *Indications for use.* Improved feed efficiency.

(b) *Limitations.* (1) Feed only to cattle being fed in confinement for slaughter. Feed continuously in complete feed at a rate of 50 to 360 milligrams of monensin per head per day; as monensin sodium. Complete feeds may be manufactured from monensin liquid Type B feeds. The liquid Type B feeds have a pH of 4.3 to 7.1 and their labels must bear appropriate mixing directions as defined in paragraph (d)(12) of this section. The liquid feed must bear caution statement as follows: Inadequate mixing, (recirculation or agitation), of liquid feeds has resulted in increased monensin concentration which has been fatal to cattle.

(2) An approved physically stable monensin liquid feed will not be subject to the requirements for mixing directions defined in paragraph (d)(12) of this section. A manufacturer may secure approval of a physically stable liquid feed by:

(i) Either filing an NADA for the product or by establishing a master file containing data to support the stability of its product;

(ii) Authorizing the agency to reference and rely upon the data in the master file to support approval of a supplemental NADA to establish physical stability; and

(iii) Requesting No. 000986 in § 510.600(c) of this chapter to file a supplemental NADA to provide for the use of its monensin Type A article in the manufacture of the liquid feed specified in the appropriate master file. If the

data demonstrate the stability of the liquid feed described in the master file, the agency will approve the supplemental NADA. The approval will provide a basis for the individual liquid feed manufacturer to manufacture the liquid medicated feed under a medicated feed mill license described in the master file. A manufacturer who seeks to market a physically unstable monensin liquid feed with mixing directions different from the standard established in paragraph (d)(12) of this section may also follow this procedure.

(ii) *Amount per ton.* Monensin, 5 to 30 grams, plus tylosin, 8 to 10 grams.

(a) *Indications for use.* Improved feed efficiency; for reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Actinomyces (Corynebacterium) pyogenes*.

(b) *Limitations.* Feed only to cattle being fed in confinement for slaughter. Feed continuously as sole ration at the rate of 50 to 360 milligrams of monensin and 60 to 90 milligrams of tylosin per head per day; as monensin sodium; as tylosin phosphate. Combination drug liquid Type B medicated feeds may be used to manufacture dry Type C medicated feeds and shall conform to mixing instructions as in § 558.625 (c).

(iii) *Amount per ton.* Monensin, 25 to 400 grams.

(a) *Indications for use.* For increased rate of weight gain; for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*.

(b) *Limitations.* Feed to pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers). For increased rate of weight gain, feed at a rate of 50 to 200 milligrams monensin per head per day in not less than 1 pound of feed or, after the 5th day, feed at a rate of 400 milligrams per head per day every other day in not less than 2 pounds of feed. For prevention and control of coccidiosis, feed at a rate of 0.14 to 0.42 milligram per pound of body weight per day, depending on severity of challenge, up to 200 milligrams per head per day. During first 5 days of feeding, cattle should receive no more than 100 milligrams per day in not less than 1 pound of feed.

(iv) [Reserved]

(v) *Amount.* 150 milligrams per pound (0.033 percent).

(a) *Indications for use.* For increased rate of weight gain and for prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*.

(b) *Limitations.* As protein-mineral blocks to be fed free choice to cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers) on pasture which may require supplemental feed. Provide 50 to 200 milligrams of monensin (0.34 to 1.33 pounds) per head per day, at least 1 block per 10 to 12 head of cattle. Roughage must be available at all times. Do not allow animals access to other protein blocks, salt or mineral, while being fed this product. Do not allow horses or other equines access to formulations containing monensin (ingestion of monensin by equines has been fatal). Block's effectiveness in cull cows and bulls has not been established. Approval must comply with § 510.455 of this chapter.

(vi) *Amount per ton.* Monensin, 25 to 400 grams.

(a) *Indications for use.* For improved feed efficiency; for prevention and control of coccidiosis due to *E. bovis* and *E. zuernii*.

(b) *Limitations.* Feed to mature reproducing beef cows. Feed as supplemental feed, either hand-fed in a minimum of 1 pound of feed or mixed in a total ration. For improved feed efficiency, feed continuously at a rate of 50 to 200 milligrams monensin per head per day. For prevention and control of coccidiosis, feed at a rate of 0.14 to 0.42 milligram per pound of body weight per day, depending upon severity of challenge, up to a maximum of 200 milligrams per head per day. During first 5 days of feeding, cattle should receive no more than 100 milligrams per head per day.

(vii) *Amount per ton.* Monensin, 10 to 30 grams.

(a) *Indications for use.* For prevention and control of coccidiosis due to *E. bovis* and *E. zuernii*.

(b) *Limitations.* For feedlot cattle, feed at a rate of 0.14 to 0.42 milligram per pound of body weight per day, de-

pending upon the severity of challenge, up to maximum of 360 milligrams per head per day.

(viii) *Additional combinations.* Monensin may be used for heifers being fed in confinement for slaughter with melengestrol acetate with or without tylosin as in § 558.342.

(ix) *Amount.* To 000986: To make liquid Type B medicated feed containing 400 grams per ton monensin sodium with 150 grams per ton tylosin phosphate used to make a dry Type C medicated feed containing 21.4 to 26.8 grams per ton monensin plus 8 to 10 grams per ton tylosin.

(a) *Indications for use.* Improved feed efficiency; for reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Actinomyces (Corynebacterium) pyogenes*.

(b) *Limitations.* Feed only to cattle being fed in confinement for slaughter. Feed continuously at the rate of 8.2 to 10.2 kilograms (18 to 22.5 pounds) of Type C medicated feed per head per day to supply 240 milligrams of monensin and 90 milligrams of tylosin per head per day; as monensin sodium; as tylosin phosphate. Do not allow horses or other equines access to feeds containing monensin. Ingestion of monensin by equines has been fatal. Safe use in unapproved species and breeding cattle has not been established. The liquid medicated feed must bear expiration date of 14 days after date of manufacture. The mixing directions for this liquid medicated feed stored in recirculation or agitation tank systems are as defined in paragraph (d)(12) of this section.

(x) *Amount per ton.* Monensin, 1,620 grams as monensin sodium (810 milligrams per pound).

(a) *Indications for use.* For increased rate of weight gain; and for prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii* in pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers).

(b) *Specifications.* Use as free-choice Type C medicated feed formulated as mineral granules as follows:

Ingredient	Percent	International feed no.
Monocalcium phosphate (21% phosphorus, 15% calcium)	29.49	6-01-082
Sodium chloride (salt)	24.25	6-04-152

Ingredient	Percent	International feed no.
Dried cane molasses	20.0	4-04-695
Ground limestone (33% calcium) or calcium carbonate (38% calcium)	13.75	6-02-632
Cane molasses	3.0	4-04-696
Processed grain by-products (as approved by AAFCO)	5.0	
Vitamin/trace mineral premix ¹	2.5	
Monensin Type A article, 80 grams per pound	1.01	
Antidusting oil	1.0	

¹Content of the vitamin/trace mineral premix may be varied. However, they should be comparable to those used for other free-choice feeds. Formulation modifications require FDA approval prior to marketing. The amount of selenium and ethylenediamine dihydroiodide (EDDI) must comply with the published requirements. (For selenium see 21 CFR 573.920; for EDDI see 51 FR 11483 (April 3, 1986).)

(c) *Limitations.* For free-choice feeding to pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers) at a rate of 50 to 200 milligrams per head per day. During the first 5 days of feeding, cattle should receive no more than 100 milligrams per day. Do not feed additional salt or minerals. Do not mix with grain or other feeds. Monensin is toxic to cattle when consumed at higher than approved levels. Stressed and/or feed- and/or water-deprived cattle should be adapted to the pasture and to unmedicated mineral supplement before using the monensin mineral supplement. Do not feed to lactating dairy cattle. The product's effectiveness in cull cows and bulls has not been established. Consumption by unapproved species may result in toxic reactions. A feed manufacturing facility must possess a medicated feed mill license issued under §515.20 of this chapter in order to manufacture this free-choice Type C feed.

(xi) *Amount per ton.* Monensin, 10 to 200 grams.

(a) *Indications for use.* For prevention and control of coccidiosis due to *E. bovis* and *E. zuernii*.

(b) *Limitations.* For calves excluding veal calves. Feed at a rate of 0.14 to 1.0 milligram monensin per pound of body weight per day, depending upon the severity of challenge, up to maximum of 200 milligrams per head per day.

(xii) *Amount per ton.* Monensin, 10 to 30 grams; plus tylosin, 8 to 10 grams.

(a) *Indications for use.* For improved feed efficiency, prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*, and reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Actinomyces (Corynebacterium) pyogenes*.

(b) *Limitations.* Feed only to cattle being fed in confinement for slaughter. Feed continuously to provide 50 to 360 milligrams monensin per head per day. For prevention and control of coccidiosis, feed at a rate of 0.14 to 0.42 milligram monensin per pound of body weight per day, depending upon the severity of challenge, up to maximum of 360 milligrams per head per day; and 60 to 90 milligram of tylosin per head per day.

(xiii) *Amount per ton.* Monensin, 11 to 22 grams.

(A) *Indications for use.* For increased milk production efficiency (production of marketable solids-corrected milk per unit of feed intake) in dairy cows.

(B) *Limitations.* Feed continuously to dry and lactating dairy cows in a total mixed ration ("complete feed"). See paragraphs (d)(2), (d)(5), (d)(6), (d)(7)(i), (d)(7)(ii), (d)(7)(iii), (d)(7)(vi), (d)(8), and (d)(12) of this section.

(4) *Replacement chickens intended for use as cage layers—(i) Amount per ton.* Monensin, 90 to 110 grams.

(i)(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(ii) *Amount per ton.* Monensin, 90 to 110 grams; plus bacitracin methylene disalicylate, 4 to 50 grams.

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; for increased rate of weight gain, and improved feed efficiency.

(b) *Limitations.* Feed continuously as sole ration. Do not feed to chickens over 16 weeks of age. Do not feed to laying chickens. As monensin sodium

provided by 000986; bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.

(iii) *Amount per ton.* Monensin, 90 to 110 grams; plus bacitracin methylene disalicylate, 50 grams.

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; and as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

(b) *Limitations.* Feed continuously as sole ration. Do not feed to chickens over 16 weeks of age. Do not feed to laying chickens. As monensin sodium provided by 000986; bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.

(iv) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; as monensin sodium; do not feed to chickens over 16 weeks of age.

(v) *Amount per ton.* Monensin, 90 to 110 grams; plus bacitracin methylene disalicylate, 100 to 200 grams.

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; and as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

(b) *Limitations.* Feed continuously as sole ration. Do not feed to chickens over 16 weeks of age. Do not feed to laying chickens. To control necrotic enteritis, start medication at first clinical signs of disease; vary dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 grams per ton). As monensin sodium provided by 000986; bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.

(vi) *Amount per ton.* Monensin, 90 to 110 grams; bacitracin methylene disalicylate, 50 grams; plus roxarsone, 22.7 to 45.4 grams.

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; as an aid in the prevention of necrotic enter-

itis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin; and for increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(b) *Limitations.* Feed continuously as sole ration. Do not feed to laying chickens. Use as sole source of organic arsenic. Do not feed to chickens over 16 weeks of age. Poultry should have access to drinking water at all times. Drug overdosage or lack of water may result in leg weakness or paralysis. Withdraw 5 days before slaughter. As monensin sodium provided by 000986; bacitracin methylene disalicylate and roxarsone as provided by 046573 in § 510.600(c) of this chapter.

(vii) *Amount per ton.* Monensin, 90 to 110 grams; bacitracin methylene disalicylate, 100 to 200 grams; plus roxarsone, 22.7 to 45.4 grams.

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin; and for increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(b) *Limitations.* Feed continuously as sole ration. To control necrotic enteritis, start medication at first clinical signs of disease; vary bacitracin dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 grams/ton). Do not feed to laying chickens. Use as sole source of organic arsenic. Do not feed to chickens over 16 weeks of age. Poultry should have access to drinking water at all times. Drug overdosage or lack of water may result in leg weakness or paralysis. Withdraw 5 days before slaughter. As monensin sodium provided by 000986; bacitracin methylene disalicylate and roxarsone as provided by 046573 in § 510.600(c) of this chapter.

(iv) *Amount per ton.* Monensin, 90 to 110 grams, plus roxarsone, 22.7 to 45.4 grams.

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E.*

maxima, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(b) *Limitations.* Feed continuously as sole ration. Use as sole source of organic arsenic. Withdraw 5 days before slaughter. Do not feed to laying chickens. Do not feed to chickens over 16 weeks of age. Poultry should have access to drinking water at all times. Drug overdosage or lack of water may result in leg weakness or paralysis. As monensin sodium provided by 000986; roxarsone as provided by 046573 in § 510.600(c) of this chapter.

(5) *Bobwhite quail*—(i) *Amount per ton.* Monensin, 73 grams.

(ii) *Indications for use.* For the prevention of coccidiosis in growing bobwhite quail caused by *Eimeria dispersa* and *E. Lettyae*.

(iii) *Limitations.* Feed continuously as the sole ration; do not allow horses, other equines, mature turkeys, or guinea fowl access to feed containing monensin.

(6) *Goats*—(i) *Amount per ton.* Monensin, 20 grams.

(a) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria crandallis*, *E. christenseni*, and *E. ninakohlyakimovae*.

(b) *Limitations.* (1) Feed only to goats being fed in confinement. Do not feed to lactating goats. Feed continuously in Type C feed as monensin sodium. Type C feed may be manufactured from monensin liquid Type B feeds. The liquid Type B feeds have a pH of 4.3 to 7.1 and their labels must bear appropriate mixing directions, as defined in paragraph (d)(12) of this section. The liquid feed must bear caution statement as follows: Inadequate mixing, (recirculation or agitation), of liquid feeds has resulted in increased monensin concentration which could be fatal to goats.

(2) An approved physically stable monensin liquid feed will not be subject to the requirements for mixing directions defined in paragraph (d)(12) of this section. A manufacturer may secure approval of a physically stable liquid feed by:

(i) Either filing an NADA for the product or by establishing a master file containing data to support the stability of its product;

(ii) Authorizing the agency to reference and rely upon the data in the master file to support approval of a supplemental NADA to establish physical stability; and

(iii) Requesting No. 000986 in § 510.600(c) of this chapter to file a supplemental NADA to provide for the use of its monensin Type A article in the manufacture of the liquid feed specified in the appropriate master file. If the data demonstrate the stability of the liquid feed described in the master file, the agency will approve the supplemental NADA. The approval will provide a basis for the individual liquid feed manufacturer to manufacture the liquid medicated feed under a medicated feed mill license described in the master file. A manufacturer who seeks to market a physically unstable monensin liquid feed with mixing directions different from the standard established in paragraph (d)(12) of this section may also follow this procedure.

(ii) [Reserved]

(7) Monensin may also be used in combination with:

(i) Decoquinatone alone or with tylosin as in § 558.195.

(ii) Melengestrol acetate alone or with tylosin as in § 558.342.

(iii) Ractopamine alone or in combination as in § 558.500.

[40 FR 13959, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.355, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 558.360 Morantel tartrate.

(a) *Approvals.* Type A medicated articles: 88 grams per pound to 066104 in § 510.600(c) of this chapter.

(b) *Related tolerances.* See § 556.425 of this chapter.

(c) *Special considerations.* (1) Do not use in Type B or Type C medicated feeds containing bentonite.

(2) Consult your veterinarian before using in severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

(d) *Conditions of use*—(1) *Amount.* 0.44 to 4.4 grams of morantel tartrate per pound of feed.